DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service 93196

Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

May 22, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
Ref. KAN-2002-04

Mr. Mark A. Reser
Chief Operating Officer
Reser's Fine Foods, Inc.
15570 S.W. Jenkins Rd.
Beaverton, OR 97006

Dear Mr. Reser:

We inspected your firm, located at 3167 S.E. 10th St., Topeka, KS 66607, on February 21, 26, 27 & March 5, 2002, and found that you have serious deviations from the Seafood HACCP regulations, Title 21 Code of Federal Regulations Part 123 (21 CFR 123) and Good Manufacturing Practices (21 CFR 110). These deviations cause your seafood salads to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations are as follows:

- Your firm must conduct a hazard analysis to determine the food safety hazards that are reasonably likely to occur and have a written HACCP plan that lists these food safety hazards to comply with 21 CFR 123.6(a) and 21 CFR 123.6(c)(1). However, your firm's HACCP plan for seafood salads does not list the food safety hazards that are associated with:

  a. Pathogen growth and the formation of *Clostridium botulinum* toxin in vacuum packed surimi (imitation crab) that is used as an ingredient in some of your seafood salads. Specifically, your HACCP plan should include critical control points for pathogen growth and the formation of *Clostridium botulinum* at receiving and refrigerated storage. The *Clostridium botulinum* hazard exists as long as the surimi is vacuum packaged.

  In addition, your HACCP plan for seafood salads should control the hazard of pathogen growth during processing. Control of the pathogens during processing is accomplished by limiting or eliminating the length of time the raw materials and the finished product are exposed to temperatures above 40°F.

Note: The surimi (imitation crab) is a Pasteurized, vacuum packaged, ready to eat product that requires a temperature critical limit of not more than 40°F at the receiving and storage critical control points.

b. Metal inclusion resulting from the mechanical devices used in the production of seafood salads.

c. Sulfite hazard resulting from the fact that sulfiting agents may be added to the shrimp used as raw material in your salads containing shrimp.

- You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11. However, your firm did not monitor the safety of water [21 CFR 123.11(b)(1)] and the protection of food, food packaging material and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical and biological contaminates [21 CFR 123.11(b)(5)]. This is evidenced by the following sanitation deficiencies found by the investigator:

a. There were no back flow prevention devices attached to several of the water spigots in the facility.

b. The investigator witnessed an employee using a high pressure washer water hose to clean a drain in the processing room floor. The contaminated water splashed onto several food contact surfaces including baskets used in the salad spinner. Ready-to-eat spinach was put inside the spinner basket without it being washed and sanitized.

c. The investigator found peeling paint on the ceiling on production areas directly over exposed ready to eat salad ingredients and food contact surfaces.

- You must have sanitation control records that, at a minimum, document the monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm maintained records that are inadequate. Your firm's sanitation control record identified as "Daily Process Deficiency Log" does not document that your firm has monitored all eight sanitation steps with sufficient frequency.

Other objectionable conditions were brought to your firm's attention and listed on the Form FDA 483 - Inspectional Observations issued to the Plant Manager at the conclusion of the inspection. These observations included peeling paint directly above food contact surfaces, improper equipment cleaning and sanitation, and lack of back flow prevention devices on all waterhoses within the facility.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your HACCP plan, copies of temperature monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations (21 CFR 123) and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your written reply to the Food and Drug Administration, Attention: Nadine Nanko Johnson, Compliance Officer, P. O. Box 15905, Lenexa, KS 66285-5905.

Sincerely,

Charles W. Sedgwick
District Director
Kansas City District

cc: Tony W. Kunis, General Manager
Reser's Fine Foods, Inc.
3167 S.E. 10th St.
Topeka, KS 66607